

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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:
EMED TECHNOLOGIES CORP., :
Plaintiff, :
:
-against- :
:
REPRO-MED. SYSTEMS, INC., :
Defendant. :
----- X

18 Civ. 5880 (LGS)

OPINION AND ORDER

LORNA G. SCHOFIELD, District Judge:

Plaintiff EMED Technologies (“EMED”) alleges that Defendant Repro-Med Systems, Inc. (“RMS”) infringed United States Patent No. 9,808,576 (the “‘576 Patent”), titled “Devices and Methods for Protecting a User from a Sharp Tip of a Medical Needle.” The ‘576 patent relates to a device that sheaths a medical needle within a protective pair of folding wings during and after the removal of the needle from the patient’s skin. The parties have presented their proposed constructions of the ‘576 Patent’s claims pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). The following sets forth the Court’s construction of the disputed terms. The Court adopts Defendant’s construction of disputed term 1, and Plaintiff’s construction of disputed terms 2 and 3. Terms 4 and 5 do not require any construction.

I. BACKGROUND

The disputed patent relates to a medical device that aids in the treatment of Primary Immunodeficiency Disease (“PIDD”). Individuals with PIDD require immunoglobulin (human plasma and antibodies) to lead normal lives. Immunoglobulin is commonly administered to patients in their homes through under-the-skin infusions, known as Subcutaneous Immunoglobulin (“SCIg”) therapy. In SCIg therapy, mechanical infusion pumps deliver the immunoglobulin via plastic tubing and subcutaneous needles. At issue here is the ‘576 patent,

titled “Devices and Methods for Protecting a User from a Sharp Tip of a Medical Needle.”

Claim 1 of the ‘576 patent describes:

A device for protecting a user from a sharp tip of a winged medical needle, the device comprising:

a central body portion;

a winged medical needle located in the central body portion; the winged medical needle having a first end in fluid connection with a delivery tube, and a second end distal from the central body portion including the sharp tip; wherein the winged medical needle is substantially perpendicular to the delivery tube;

a pair of wings, each wing of the pair of wings having an inner region and an outer region, the inner region of each wing in attachment to the central body portion, the outer region of each wing extending away from the central body portion, and the pair of wings being selectively positionable from an open position to a closed position, where the wings in an open position are spaced apart from each other to expose the medical needle to allow placement of the medical needle into a treatment site and delivery of a medicinal fluid;

. . . a mechanical fastener disposed on at least one wing of the pair of wings, the mechanical fastener configured to selectively attach the pair of wings together in the closed position with the medical needle positioned therebetween to protect against accidental needle stick injury from the sharp tip of the medical needle;

the mechanical fastener consisting of a lip extending along at least a portion of a perimeter of at least one wing of the pair of wings, and a mating portion along a perimeter of at least one other wing of the pair of wings, and wherein the mating portion and the lip are configured to align with at least one wing relative to the at least one other wing in the closed position.

(Emphasis added to indicate disputed portions.) Figures 10 and 11 depict views of an embodiment of the claimed invention of the ‘576 patent.¹

¹ In Figure 10, 1024 is a mechanical fastener, which may also include a lip 1042 extending from a portion of perimeter 1040 of one or both wings. Recessed portion 1038 and lip 1042 may be configured to engage with one another to selectively attach the pair of wings 216, 218 together with medical needle 206 positioned between wings 216, 218. This attachment of the wings protects a user from sharp tip 212 of medical needle 206.

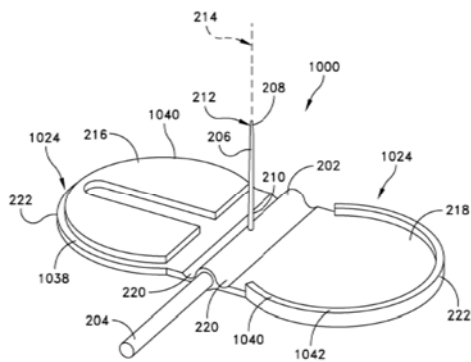


FIGURE 10

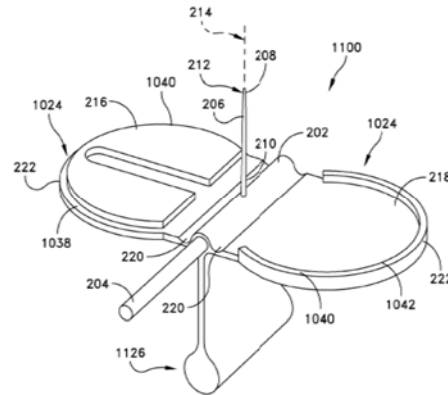


FIGURE 11

The parties initially disputed six terms. At the claim construction hearing on May 21, 2019, the parties agreed that “a mating portion along *a perimeter* of at least one other wing of the pair of wings, and wherein the mating portion and the lip are *configured* to align the at least one wing relative to the at least one other wing in the closed position” means “a mating portion along *an outer boundary* of at least one other wing of the pair of wings, and wherein the mating portion and the raised edge are *designed* to align the at least one wing relative to the at least one other wing in the closed position.” Accordingly, the term is no longer disputed.

II. STANDARD

“A district court’s duty at the claim construction stage is. . . to resolve a dispute about claim scope that has been raised by the parties.” *Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d 1314, 1319 (Fed. Cir. 2016). “This means that, as to claim coverage, the district court must instruct the jury on the meanings to be attributed to all disputed terms used in the claims in suit so that the jury will be able to ‘intelligently determine the questions presented.’” *Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1366 (Fed.Cir.2004) (citation omitted); *accord Eon Corp. IP holdings*, 815 F.3d at 1319.

“Claim construction seeks to ascribe the ‘ordinary and customary meaning’ to claim terms as a person of ordinary skill in the art would have understood them at the time of invention.” *SRI Int’l, Inc. v. Cisco Sys., Inc.*, 918 F.3d 1368, 1376 (Fed. Cir. 2019) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc)). During claim construction, the court looks “first to intrinsic evidence, and then, if necessary, to the extrinsic evidence.” *TEK Glob., S.R.L. v. Sealant Sys. Int’l, Inc.*, 920 F.3d 777, 780 (Fed. Cir. 2019) (citing *Phillips*, 415 F.3d at 1303).

The intrinsic record comprises the claims, the specification, and the prosecution history. *TEK Glob., S.R.L.*, 920 F.3d at 780. The claims themselves “provide substantial guidance as to the meaning of particular claim terms.” *Cont’l Circuits LLC v. Intel Corp.*, 915 F.3d 788, 796 (Fed. Cir. 2019) (quoting *Phillips*, 415 F.3d at 1314). Claim terms are generally “given their ordinary and customary meaning” as “understood by a person of ordinary skill in the art at the time of invention.” *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1358 (Fed. Cir. 2017) (citations omitted). The ordinary meaning of a claim term is its meaning “to the ordinary artisan after reading the entire patent.” *Id.* (citation omitted).

If a claim term does not have an ordinary meaning, it must “be read in view of the specification.” *Cont’l Circuits LLC*, 915 F.3d at 796. “Accordingly, the specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). In addition to the specification, “a court ‘should [] consider the patent’s prosecution history, if it is in evidence.’” *Id.* (quoting *Markman*, 52 F.3d at 980). “Like the specification, the prosecution history provides evidence of how the [United States

Patent and Trademark Office (“PTO”)] and the inventor understood the patent.” *Id.* (alteration in original).

Secondary to the intrinsic evidence is the extrinsic evidence, which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Phillips*, 415 F.3d at 1317. “While extrinsic evidence can shed useful light on the relevant art. . . it is less significant than the intrinsic record in determining the legally operative meaning of disputed claim language.” *Cont’l Circuits LLC*, 915 F.3d at 799 (internal quotation marks omitted).

III. DISCUSSION

The parties dispute five terms.² The first term relates to the “mechanical fastener” and the remaining four terms relate to the “winged medical needle.”

A. Mechanical Fastener

1. Consisting of (Term 1)

The parties dispute the meaning of “[t]he mechanical fastener consisting of a lip extending along at least a portion of a perimeter of at least one wing of the pair of wings.” At issue is whether “consisting of” in the body of the claim is a closed term. Plaintiff argues that the term “consisting of” in the body of Claim 1 does not limit the components of the device to the disclosed elements. Defendant asserts that “consisting of” is a “closed-ended exclusive term.” Defendant is correct.

² At the May 21, 2019, claim construction hearing, Plaintiff stated that the proposed constructions in the slide presentation at Docket No. 114 supersede all prior submissions. To the extent that Defendant’s slide presentation from the claim construction hearing at Docket No. 113 differ from the claim construction statement at Docket No. 96, the Court relies on the presentation.

“‘Consisting of’ is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim.” *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1358 (Fed. Cir. 2016) (citation omitted); *see, e.g., AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003) (finding that a patent calling for coating of stainless steel with metal “consisting essentially of aluminum” constituted a closed-ended limiting statement). By contrast, “‘comprising’ creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrecited elements.” *Id.* “[T]o overcome the exceptionally strong presumption that a claim term set off with ‘consisting of’ is closed to unrecited elements, the specification and prosecution history must unmistakably manifest an alternative meaning.” *Id.*; *see also Shire Dev., LLC v. Watson Pharm., Inc.*, 848 F.3d 981, 984 (Fed. Cir. 2017).

Here, the use of “consisting of” in the body of the claim limits that clause to the elements following the term, particularly because the transitional phrase joining the preamble with the body of the claim contains “comprising.” *See Multilayer Stretch Cling Film Holdings, Inc.*, 831 F.3d at 1358–59 (“We are unaware of any case that has construed a patent claim’s use of ‘consisting of’ to have the same open meaning as ‘comprising.’”); *Digene Corp. v. Third Wave Techs., Inc.*, 323 F. App’x 902, 909 (Fed. Cir. 2009) (summary order) (“If the term ‘consists of’ appears in the body of a claim, it does not limit the entire claim as such, but it does limit the clause for which it acts as a transition to only those elements found in that particular clause.”); *Manual of Patent Examining Procedure* at § 2111.03(II) (Jan. 2018) (“When the phrase ‘consists of’ appears in the clause of the body of a claim, rather than immediately following the preamble, there is an exceptionally strong presumption that a claim term set off with ‘consisting of’ is closed to unrecited elements.”).

Nor do the specification or prosecution history “unmistakably manifest an alternative meaning.” *See Multilayer Stretch Cling Film Holdings, Inc.*, 831 F.3d at 1358. Indeed, the prosecution history suggests that “consisting of” is a closed term. During the prosecution of the ‘576 patent, the PTO initially rejected Plaintiff’s proposed language that described the mechanical fastener as “including a mating portion along a perimeter . . .” (emphasis added). *See Regeneron Pharm., Inc. v. Merus N.V.*, 864 F.3d 1343, 1352 (Fed. Cir. 2017), *cert. denied*, 139 S. Ct. 122 (2018), (stating that “including” is “synonymous with” “comprising”). The prosecution history reveals that Plaintiff agreed with the Examiner’s suggestion to clarify Claim 1 “to specifically say the mechanical fastener *consists of* a lip or the mechanical fastener is *only* a lip. . . in an effort to overcome the prior art of record.” (emphasis added). After Plaintiff amended the mechanical fastener element to replace “including” with “consisting of,” the patent was approved. Accordingly, the prosecution history shows that Plaintiff intentionally narrowed the scope of the mechanical fastener claim to include only (1) a lip extending along at least a portion of a perimeter of at least one wing of the pair of wings, and (2) a mating portion along a perimeter of at least one other wing of the pair of wings. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) (“The purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution . . . [this] ensures that claims are not construed one way in order to obtain their allowance and in a different way against accused infringers.”); *accord Aylus Networks*, 856 F.3d at 1360.

Plaintiff’s initial application included a broader definition of mechanical fastener, and Plaintiff argues that the specification contemplates alternative types of mechanical fasteners than that listed in Claim 1 such that “consisting of” cannot be a closed term. As discussed above, however, Plaintiff’s decision during prosecution to replace “including” with “consisting of”

narrowed the scope of the mechanical fastener claim. The specification predates the amendment to the claim, and the discussion of alternative mechanical fastener structures in the specification does not overcome the limitations in Claim 1. *See Phillips*, 415 F.3d at 1312 (“We look to the words of the claims themselves. . . to define the scope of the patented invention”) (citation omitted). The ‘576 Patent states, “It is to be understood that the scope of the invention is to be determined by the scope of the claims as issued. Nothing in this Summary or the Background is to be construed as requiring a feature set forth herein or that a given embodiment address issues identified in the Background.” Here, the language of the claim governs and limits the scope of the mechanical fastener claim in accordance with Defendant’s proposed construction.

B. Winged Medical Needle Terms

1. Winged medical needle (Term 2)

Defendant argues that the term “winged medical needle” is indefinite, which renders the ‘576 Patent claims invalid. The term is not indefinite. A patent is invalid for indefiniteness “if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). The key question is whether the claims -- as opposed to particular claim terms -- inform a skilled reader with reasonable certainty about the scope of the invention. *Cox Commc’ns, Inc. v. Sprint Commc’n Co. LP*, 838 F.3d 1224, 1231 (Fed. Cir. 2016) (citation omitted). Here, the written description, combined with the intrinsic and extrinsic evidence, are sufficient to inform a person of ordinary skill in the art to understand, with reasonable certainty, the definition of a “winged medical needle.”

Defendant argues that “winged medical needle” represents “added new matter prohibited by 35 U.S.C. §132.”³ Specifically, Defendant argues that EMED changed “medical needle” to “winged medical needle” to differentiate over prior patents, and that this “change introduced a new species of medical needle, one that is undefined in the specification and unknown to any of EMED’s prior patents, as well as distinct from the generic ‘medical needle’ it replaced,” such that “there is no basis in the intrinsic evidence to construe ‘winged medical needle.’”

The prosecution history, however, evinces no intention to introduce “new matter” or change the meaning of “medical needle.” *See* 35 U.S.C. § 132(a). Defendant’s argument ignores that Plaintiff did more than add “winged” to overcome prior art. Plaintiff added “a winged medical needle located in the central body portion. . . wherein the winged medical needle is substantially perpendicular to the delivery tube.” Thus, the prosecution history makes clear that the changes to the ‘576 patent specified the location of the medical needle relative to the rest of the invention rather than amending the meaning of “medical needle.” *See Cont’l Circuits LLC*, 915 F.3d at 798–99 (Fed. Cir. 2019) (“[C]learly describing a particular claim term to overcome an indefiniteness or written description rejection is not the same as clearly disavowing claim scope.”).

³ Under 35 U.S.C. § 132(a):

Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

Defendant also argues Plaintiff's adding "winged" to the term "medical needle," would cause one skilled in the art to "understand that a 'winged medical needle' is a different element from 'each wing' 'the wings' or a/the 'pair of wings' that appear separately in [C]laim 1 as being attached to the central body portion." Defendant's argument suggests that Claim 1 contemplates four wings, not two. Defendant's argument is inconsistent with Claim 1, the specification and the prosecution history. Read in its totality, Claim 1 describes a medical needle with one pair of wings. The Claim repeatedly refers to one "pair of wings." The Claim also describes the "pair of wings . . . with the medical needle positioned therebetween." It is clear from this description that the "pair of wings . . . with the medical needle positioned therebetween" is the same as "the winged medical needle." Thus, nothing in the Claim suggests that there is more than one pair of wings. Moreover, neither the prosecution history nor the specification suggests that the "winged medical needle" is a component distinct from the separately identified "pair of wings" in the Claim. The declaration of Ron Stoker, Plaintiff's expert during the inter partes review,⁴ defines "winged needle" as a "needle with two bilateral flexible wings" (emphasis added), and none of the embodiments in the specification describe a needle with four wings. For example, the specification describes:

In an embodiment, a device 1000 (fig. 10) may include a mechanical fastener 1024 with one or both of the wings 216, 218 forming a recessed portion 1038 adjacent a perimeter 1040 . . . medical needle 206 positioned between wings 216, 218. This attachment of the wings 216, 218 protects a user from sharp tip 212 of medical needle 206.

"The specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Cont'l Circuits LLC*,

⁴ Inter partes review, sometimes known as "IPR," is a procedure for challenging the validity of a patent before the PTO.

915 F.3d at 796); *see also* *GPNE Corp. v. Apple Inc.*, 830 F.3d 1365, 1370–71 (Fed. Cir. 2016) (“We have recognized that when a patent repeatedly and consistently characterizes a claim term in a particular way, it is proper to construe the claim term in accordance with that characterization.”) (internal quotation marks omitted).

In the alternative, Defendant proposes that the term means “[t]wo bilateral wings attached to a medical needle.” Plaintiff contends that a “winged medical needle” means “[a] medical needle with two attached bilateral wings.” As there is no meaningful distinction between the proposed constructions, Plaintiff’s construction is adopted.⁵

2. Winged Medical Needle Located in the Central Body Portion (Term 3)

Plaintiff argues that “winged medical needle located in the central body portion” means “a medical needle with two attached bilateral wings extending from the central body portion.” Defendant proposes that the phrase means “the structure provided by the medical needle with the two bilateral wings attached thereto, is itself attached to the central body portion.”

Plaintiff’s construction is consistent with the specification and is therefore adopted. *See Cont’l Circuits LLC*, 915 F.3d at 796. The specification repeatedly describes, “[A] medical needle having a first end and a second end in opposition to one another, the first end in fluid connection with the central body portion and the delivery tube, and the second end of the needle extending away from the central body portion to a sharp tip.” Figures 10 and 11 “depict a medical needle extending away in a perpendicular fashion from the central body portion.”

Defendant concedes that “[a]t best, a person of ordinary skill in the art might guess that at least

⁵ To the extent that Defendant’s proposed construction of disputed terms 3, 4 and 5 rely on Defendant’s proposed construction of “winged medical needle,” Defendant’s construction is rejected for the reasons stated above.

some portion of the winged medical needle needs to extend outwardly from the central body portion [and] some part must be attached to the central body portion”

Defendant argues that Plaintiff’s proposed construction “would introduce uncertainty about what is extending from the central body portion.” The plain language of the sentence -- in addition to the figures in the specification -- indicate that the “winged medical needle” extends from the central body portion. Accordingly, the specification clearly contemplates a needle extending from a central body portion.

3. Winged Medical Needle Having a First End in Fluid Connection With a Delivery Tube (Term 4)

Plaintiff argues that “the winged medical needle having a first end in fluid connection with a delivery tube” needs no construction. Defendant argues that the term means that the “delivery tube provides fluid that is delivered directly or indirectly to the first end of the structure provided by the medical needle with the two bilateral wings attached thereto.”

No construction is necessary. “A patentee is normally entitled to the full scope of its claim language, and a departure from this general rule may be warranted only where the patentee either clearly sets forth a different definition of a claim term in the specification or disavows the full scope of the claim term during prosecution.” *Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, 914 F.3d 1347, 1364 (Fed. Cir. 2019) (internal quotation marks and citation omitted); *see also Phillips*, 415 F.3d at 1314 (“In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.”).

The plain language of Claim 1 does not require that “fluid is delivered directly or indirectly to the first end of the structure provided by the medical needle.” Defendant argues that

the prosecution history supports Defendant’s proposed construction. During the prosecution of Plaintiff’s application of 13/931,226, which was incorporated into the ‘576 Patent, Plaintiff replaced “in fluid connection with” with “connected with” a delivery tube. During the prosecution of the ‘703 Patent, which was incorporated by reference into the ‘576 Patent, the Examiner defined “in fluid connection” as:

[D]efining an arrangement (for example, a direct or indirect coupling, positioning, or assembly) of two (or more) elements which allows a fluid to pass from one element to another which is in fluid communication therewith. This appears to be the plain and ordinary meaning of this phrase as used in the limitation “a central body portion in fluid connection with a delivery tube” recited in claim 1 and described in the ‘703 patent.

This prosecution history cited by Defendant does not outweigh the plain language of Claim 1. *See Cont’l Circuits LLC*, 915 F.3d at 796 (“We have cautioned [] that because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.”) (internal quotation marks omitted). Moreover, the prosecution history does not shed light on the scope of the claim and does not contradict the plain and ordinary meaning of the claim. There is therefore no need to construe the term.

4. Winged Medical Needle is Substantially Perpendicular to the Delivery Tube (Term 5)

Defendant argues that “substantially perpendicular to the delivery tube” means “substantially perpendicular to some point along the flexible delivery tube.” Plaintiff argues that no construction is necessary. Plaintiff is correct.


Defendant’s construction introduces a flexibility requirement for the delivery tube that is not contained in the claim language. *See Phillips*, 415 F.3d at 1312 (“We look to the words of

the claims themselves. . . to define the scope of the patented invention.”). Although Defendant argues that the claim language is vague and its proposed construction “resolves the ambiguity,” Claim 1 describes that the winged medical needle has “a first end in fluid connection with a delivery tube . . . perpendicular to the delivery tube.” As the claim is clear that the winged medical needle is perpendicular to some point along the delivery tube, Defendant’s proposed construction is redundant. “Construing a claim term to include features of that term already recited in the claims would make those expressly recited features redundant.” *Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229, 1237 (Fed. Cir. 2016); *see also Power Mosfet Techs., L.L.C. v. Siemens AG*, 378 F.3d 1396, 1410 (Fed. Cir. 2004) (explaining that a claim construction which renders claim terms superfluous is generally disfavored).

IV. CONCLUSION

The disputed terms, as set forth in the parties’ claim construction submissions, are construed as set forth above.

Dated: June 4, 2019
New York, New York



LORNA G. SCHOFIELD
UNITED STATES DISTRICT JUDGE